United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE 15-08

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
CVB Director

BYRON RIPPKE

Digitally signed by BYRON RIPPKE
DN: c=US, o=U.S. Government, ou=Department of Agriculture, cn=BYRON RIPPKE, 0.9.2342.19200300.100.1.1=12001000004093
Date: 2015.06.10 07:38:06 -05'00'

SUBJECT: Changes to the Administrative Inspection Review Program

I. PURPOSE

The purpose of this memorandum is to inform interested parties of the changes and reimplementation of the Center for Veterinary Biologics' Administrative Inspection Review (AIR) program.

II. BACKGROUND

The AIR is designed to assist the Center for Veterinary Biologics (CVB), licensees, and permittees in maintaining accurate records, facilitate more efficient on-site inspections, and enhance regulatory compliance between the licensed entities and the Animal and Plant Health Inspection Service (APHIS). It also helps provide transparency between the CVB and licensed firms. The CVB requests information from the licensees and permittees for the AIR program in accordance with Title 9, *Code of Federal Regulations* (9 CFR), part 116.5(a).

The AIR process was suspended October 1, 2012, due to lack of resources available in the CVB to evaluate the reviews. Based on these previous experiences and a re-alignment of resources, the CVB is resuming the AIR process.

III. ACTION

The CVB will institute a rotation of AIR documentation that licensed manufacturers or permittees will complete and submit to the CVB. The AIR documents will be electronically provided to the liaison of each licensed establishment for review. Each establishment will receive one AIR regardless of the number of locations. The firms will review the information for completeness, verify for accuracy, attach any necessary paperwork, and return to the CVB within the specified time frame of 60 calendar days through electronic means provided by the CVB. Requests for extensions may be submitted to the CVB, Inspection and Compliance.

The AIR will consist of between 7 and 14 documents, depending on the year. An example of one of these documents is a listing of the manufacturer's active labels on file with the CVB. Each document will be accompanied by a detailed list of directions explaining what is expected and any documentation required by the CVB for completion.

IV. IMPLEMENTATION/ APPLICABILITY

This change is effective with the date of this Notice.